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TITLE: Secure Wireless Military Healthcare Telemedicine Enterprise System

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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

The primary objective of this research effort is to integrate ViTel Net's MedVizer™ software and Dvision Tools with cross platform telemedicine systems, inclusive of computer based systems, handheld wireless PDA devices, and miniature computers, to existing DoD legacy and developing healthcare information systems, clinical repositories, and knowledge base systems for application at the point of care. This annual report reflects a number of projects wherein the tasks defined in the SOW are being accomplished. Specific project reports referenced herein detailing the specific application, work progress, and results will be submitted as supplementary reports.

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telemedicine, patient distributed record, medical informatics, point of care, knowledge acquisition, wireless information technologies

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Table of Contents

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INTRODUCTION:

The emerging nature of telemedicine is an environment in which health care providers seek to share a vast array of medical information which is captured, disseminated and displayed in a variety of modalities ranging from email to high resolution imagery and real-time video teleconferencing. In theory clinicians should be able to select and use whatever information modalities and whatever electronic medical record systems they prefer with the technical systems integration issues of information discourse among disparate sources being transparent. The purpose of this research effort is to evaluate the use of ViTel Net's MedVizer Dvision Tools, a commercial-off-the-shelf (COTS) telemedicine integration tool for rapidly configuring and dynamically integrating disparate medical teleconsultation systems, medical information and image display modalities, and electronic medical records systems that span the continuum of the Defense Health System from the foxhole to the medical center in a secure environment. The objective is to demonstrate the use of the MedVizer Dvision Tools, a telemedicine information integration software product, for the rapid configuration of wireless and wired teleconsultation systems with legacy and emerging Department of Defense health informatics systems without need of additional conventional programming or costly systems integration efforts. Critical to the integration process is the maintenance of security requirements while operating across the spectrum of communications systems supporting the Medical Operational Continuum from the front line Medic to the fixed facility Medical Centers.

BODY:

The initial concept for the research plan as described within the Statement of Work was that each task, although related, would be able to be performed as individual tasks. As the execution of the plan began it was quickly realized that several factors, described below, were impacting on the planned approach making it difficult to execute and limiting productivity. First many of the tasks were dependent upon the availability and access to the military's legacy and emerging health information systems, access to clinical areas within selected military facilities, and access to point-of-care medical personnel at various points across the military's operational health care continuum. Second was the need to continuously adapt to the dynamics of technological changes occurring both in the biomedical and information technology fields. Third was the realization that the most appropriate and productive means of accomplishing the tasks was to identify specific meaningful projects in which there was support either within a military or civilian healthcare facility that would involve the performance application of task objectives and goals and the same time provide a means for test and evaluation.

These factors have led us to the adoption of a research approach that is responsive to project opportunities within the general context of the research design and that will insure timely and productive task accomplishments.

This revised approach continues to enable ViTel Net to apply the planned research methodology, described in our proposal, including computer modeling and simulation, followed by prototype development and bench testing. Following a successful bench test interjection of the prototype into a "live" environment wherein it can be integrated with an existing medical informatics systems for data retrieval and input process testing. The final step will be the introduction of the integrated device into field and clinical settings for testing and evaluation.

This report therefore should be viewed as an interim report which addresses each of the specific task specified in the SOW and provides a brief overview of projects that have been completed or that are in progress related to the respective research tasks. Subsequent reports will be developed for each specific project describing the concept, research approach, integration and development activities, and results of implementation and evaluation. Within these reports cross-references will be provided to the task specified in the SOW that are being implemented. Reference will be made by task and task year.

Task 1: Identify, evaluate, and finalize health care provider's patient and clinical information, and data entry requirements originating at the point of care.

It was assumed that the patient information required by the medical professional at the point of care and the type of entries that would be placed into the patient's record would be specific to and different at each level of care. Therefore three levels of medical care were assessed. The first assessment was of a neurology inpatient ward, the second assessment was within an outpatient continuous care environment where patients were being treated remotely using telemedicine technology, and the third was of an outpatient intake process within a clinical setting. As expected the clinical information requirements were different at each level with the most specific and complex considering the level of interaction with existing hospital information systems within the inpatient neurology ward application. Although, the differences in requirements were significant it was found that there were some similarities in the acquisition of a patient's condition, specifically in the area of vital signs monitoring. In general, however, it was also found that not only were the data entry requirements substantially different but that the method of entry of that data into a patient's record, in terms of responsibility, differed for each of the assessed areas. Within the neurology ward multiple professional health care providers, primarily attending physicians and ward staff members, executed all data entries. Whereas for the outpatient continuous care scenario both the attending nurse and the patient will need the capability to make data entries into the record. In the patient intake scenario all data entries were made solely by the patient. In each scenario the participants all desired, where feasible, that entries should be made electronically without need of direct manual data entry, believing such a process would result in a reduction of data entry errors.

The neurology project following the initial investigation was placed on hold due to the need to gain permission to access the legacy information systems and use of wireless technology within the Walter Reed Army Medical Center (WRAMC). Continuation of this project will require use of both wired and wireless technology for data entry and the ability to directly access several modules of the hospital information system. The complexity of this effort coupled with the time required to obtain all necessary approvals to proceed resulted in placing the project on hold while seeking appropriate authorizations. This project will be re-initiated following successful demonstration of similar applications on a smaller scale during other projects and when the security and potential electromagnetic interference issues associated with the application of wireless technology are resolved.

The second level of care, continuous care of patients on an outpatient basis, was selected as an appropriate starting point for this effort due to it being a rapid growing need within both the public and private health care sectors and that it could be accomplished in a more controlled environment. This application requires the ability to access a patient record from a database, update data entries using remote telemedicine technology, and interactive interaction between the patient and health care clinician using audio and video technology. To be practical and available to a large population the goal was to integrate ViTel Net's low bandwidth technology that would enable the accomplishment of the objectives using the standard plain old telephone (POTS) circuit. The technology to be used in such an environment must be very user friendly considering the range of technology awareness that will be exhibited by the potential population. The initial assessment demonstrated that some patients would be quite capable of performing multiple functions and be quite comfortable with the use of the technology while others will be incapable of doing much more than following basic instructions and responding verbally to the healthcare provider. Interviews were conducted with healthcare providers attending continuous care patients involving daily face-to-face home visits of the clinician to formulate the information and data entry requirements. The basic need was to have the capability to develop and maintain a longitudinal record of a patient that would reveal vital sign (blood pressure, pulse, oxygenization, and temperature), weight, blood glucose, and heart lung sound (wave forms) over time. The patient record also needed to have a means whereby a detailed registry of medication and changes in medication including dosage rates and begin and end date for each change order. Additional information considered beneficial to quality healthcare was the maintenance of a longitudinal accounting of the patient's daily condition, which would need to be acquired by both visual observations and the patient's response to specific health related questions. Ideally the patient would respond to specific questions by responding online electronically; however, an alternative means where the clinician using verbal ques would acquire the information needed to complete the daily questionnaire. In essence to meet the requirements the system needed to able to collect the same amount and detail of information remotely that is presently collected using the traditional daily home visit of a health care provider. The primary objective was to enable a health care provider to perform all functions remotely to include maintenance of a longitudinal multimedia record for each patient. An additional desired objective was to have the capability of

distributing the multimedia patient information to the patient's attending physician for review and possible consultation. The overriding objective was to enable the health care provider to provide equal or better delivery of healthcare to the patient compared to the traditional methodology. It is believed that using the technological approach for providing home health services will result in a reduction of data entry errors occurring during the traditional manual transcription process. Having completed the requirements assessment the workflow and prototype patient record was modeled using the MedVizer Tools. The model design and prototype was provided to the same health care providers used in the initial assessment for review and comment. Based upon comments received final revisions were completed. The next step involves the integration of a prototype demonstration model. See Task 3 for further discussion.

The OB-GYN Clinic at Walter Reed Army Medical Center (WRAMC), seeking to reduce the time and cost involved in intake interviews for their outpatient service, provided the third opportunity to address data collection and data entry requirements at a different level of care. The desired objective was to automate the patient registration and intake interview process using wired and wireless technology, to replace the traditional labor-intensive process currently used. It was determined that an integrated system must provide the means whereby a patient can automatically access their record, update the record with their current vital signs (blood pressure, pulse, temperature and weight), and complete an intake questionnaire describing current physical condition without any intervention by hospital personnel. The system must enable the patient's record to be immediately updated within the legacy hospital information (Composite Health Care System I [CHCSI]) using an ICDB interface, since that is the record that an attending physician will review prior to seeing the patient. Therefore the time of transfer of data from the intake station to the CHCSI database had to occur in real-time. The goal of the process is to eliminate the traditional labor-intensive method of obtaining patient information and of the manual data entry into the hospital information system. The project has been undertaken in several phases to accommodate the clinical process and to insure interoperability with the legacy HIS systems. The initial phase involves: 1) assessing the vital sign data sets that need to be electronically entered into the patient record, 2) implementing the MedVizer PostMaster as a transaction bridge to the ICDB interface to CHCSI, 3) integrating ViTel Net's electronic Vital Sign Kiosk with the MedVizer PostMaster, and 4) building, using the MedVizer tools, the XML interface to the ICDB. The second phase will involve the integration of the electronic registration. The third phase requires the integration of the patient intake questionnaire to be developed using the MedVizer tools and the integration of the data to the patient record contained in CHCSI. The project spans multiple tasks to include Task I, III, IV, and VI. To insure full compliance with existing hospital technology each phase will be developed in accordance with the model referenced above and tested within the clinical setting prior to implementation of the next phase. Phase I is ongoing. During this phase the patient will be required to scan their military identification card using ViTel Net's integrated card reader technology that will automatically initiate a transaction between the MedVizer PostMaster and the ICDB to retrieve or gain access to that patient's record. In the event it is a new patient, a new record must be created using the system. Patients will then update their record by using the electronic vital signs monitor located in the Kiosk.

The acquired data, without further intervention will be transmitted to the patient record residing in the ICDB database. This transaction will occur seamlessly using the functions of the MedVizer PostMaster interface to the ICDB. ViTel Net, with this conceptual framework, has completed the model design for the user interface and technology workflow. Using the MedVizer tools an XML interface to the ICDB is under development to enable the transaction for updating the patient record in the legacy hospital information system. The next step will be to develop a prototype demonstration model using ICDB database simulation provided by WRAMC. See Task 3 for further discussion.

Task 2: Identify and evaluate commercial off-the-shelf (COTS) medical informatics knowledge based systems pertaining to clinical requirements.

Using the Internet, as the search engine, a number of medical knowledge databases have been identified for possible application within a clinical setting. Many of the initial knowledge bases reviewed, however, were limited in application to the Palm hand held device using the OS operating system and thus failed to meet the requisite criteria for operating cross platforms that would be found within a clinical setting. In recent months many newer knowledge base systems have been identified that use the more common Microsoft Windows Operating System and thus offer the possibility for cross platform implementation. Due to the limited number of such knowledge databases currently, we have deferred further investigation until the availability of such systems develop further which will enable a more comprehensive comparative analysis of potentially usable systems. We have, however, completed and assessment of a Microsoft Windows knowledge-based system developed by our Norwegian partner for a separate USAMRMC contract. This knowledge base was evaluated and tested as a proof of concept for compatibility with the MedVizer COTS products and interoperability cross platforms. The database proved compatible and capable of operating on various Microsoft operating systems to include Windows 95, 98, 2000, and NT. However, additional development would be necessary for full cross platform compatibility, specifically with the CE operating system. Although, a respectable knowledge base system the need to further enhance the database to provide full interoperable cross platform was not deemed appropriate without further investigation of other potential knowledge bases that may require less modification. Evaluation of knowledge base data systems will continue during year 2 of the research program.

Task 3: Integrate point-of-care data collection, medical order entry, and knowledge base acquisition tools with ViTel Net's MedVizer software.

Continuous care of patients on an outpatient basis (Continued from Task 1). A prototype system integrating the MedVizer tools with commercial off the shelf (COTS) components has been completed. The prototype system uses the ViTel Net Clinical Call Center to remotely access the patient's home monitoring unit using standard plain old telephone circuits (POTS). Using the MedVizer tools a standard (COTS) Welch Allyn vital signs monitor and a Cardionics (COTS) electronic stethoscope has been integrated with a Motion Media Video Phone (COTS) and MedVizer software to form the home unit. The

home unit is totally controlled through ViTel Net's Clinical Call Center unit. This configuration was specifically designed to limit the amount of interaction required by the patient. The patient will be required only to properly place the medical device (i.e., blood pressure cuff) following the guidance given by the clinical call center operator. The clinical call center operator will be able to observe the patient's placement of the medical sensor device and direct necessary adjustments to insure accurate readings. Once properly placed the clinical call center operator will activate the medical sensor device to obtain the output readings. ViTel Net's clinical call center, using the MedVizer rapid integration tools, is configured to receive the data directly from the medical device without further patient intervention. The system is also designed to enable the clinician to review current medication dosages and enter changes to medications. A patient questionnaire has also been designed that can either be completed directly by the patient and automatically transmitted to the clinical call center or completed by the clinician based on questions asked of the patient. The questionnaire is used to assess the current condition of the patient. The data at the clinical call center is maintained in a longitudinal format to enable viewing of patient conditions over time. The clinical call center has the capability to forward patient data to the attending physician for review and consultation as needed. See Appendix 1 for system configuration and research task involved in this project. Currently the system is undergoing prototype evaluation in a beta test environment at the Medical University of South Carolina. The systems are scheduled for deployment for clinical evaluation later this calendar year.

The design configuration and work plan for implementation of the OB-GYN Outpatient Clinic, Walter Reed Army Medical Center (WRAMC), continued from Task 1, has been completed and agreed upon by all participating WRAMC agencies/departments. WRAMC is now in the process of obtaining the necessary authorizations required for the system design and implementation plan. The design concept is at Appendix 2. In a parallel process ViTel Net has completed the integration of a prototype system following the phase 1 design. The prototype system, due to the ongoing effort by WRAMC to obtain necessary authorization for interface to the legacy hospital information systems (ICDB and CHCSI), uses a simulated patient database. During the preliminary testing of the prototype it was determined that a wireless (802.11b) security system would need to be integrated prior to implementing within WRAMC. As a result Task 3, year 2 "Demonstrate interoperability of ViTel Net's Wireless MedVizer Telemedicine Products with the Fortress Technology's Air Fortress 802.11b security system" was advanced. Interoperability testing with Air Fortress 802.11b security system in a laboratory environment with a variety of MedVizer Telemedicine Products has been completed, see Appendix 3. There were no compatibility issues identified in the testing environment. The test did not, however, evaluate the level of security afforded by the Air Fortress technology but rather that interoperability between that system and MedVizer products. The test environment validated full compatibility without any degradation in quality of performance of the MedVizer products. The prototype system, currently being tested at ViTel Net now includes the Air Fortress security technology. This system has demonstrated the capability to achieve the objectives of Phase 1. ViTel Net is now in the process of refining the "User Interface" using the MedVizer Tools. The user interface must enable the patient, with limited instructions, using bar code technology to access

their record simply by swiping their military identification cared. Upon accessing and verifying that their record is correct the patient then must be able to electronically gather their vital signs, using the electronic vital signs medical device for blood pressure, pulse and temperature, the results are then automatically updated in the patient's record. The patient then will step on the electronic scale, those results will also be automatically updated in the record. Upon verifying that all fields have been completed the patient will exit their record, which will clear the system of all data. Upon exiting the system it will automatically update that patients record in the ICDB and CHSCI (now a prototype data base). The record is immediately available for review by the attending physician with all data updates. The user interface and instructions are being evaluated for ease of use prior to submission to the WRAMC project personnel for comment and approval. Concurrently, ViTel Net's engineers and WRAMC information technology team assigned to the project, are exchanging necessary data to enable the integration of the XML interface to the ICDB for accessing patient records stored in that legacy hospital information system. This interface will be tested in a laboratory environment using a simulated ICDB database provided by WRAMC. It is anticipated that Phase 1 of this project will be ready for clinical trails at WRAMC later this calendar year assuming that all necessary WRAMC approvals are granted in a timely fashion.

Task 4: Identify interoperability requirements to establish seamless connectivity to the existing DoD heath care information systems (Composite Health Care System II [CHCSII], Field Deployable Medical Record [FDMR], Personal Information Carrier [PIC], and other informatics systems.

In addition to the ongoing work to interface with the ICDB and CHCSI discussed above ViTel Net, using the MedVizer integration tool, has successfully established connectivity to the following DoD health care information systems:

a. Integration with legacy hospital information systems HIS and electronic medical records systems:
   (1) CHCSII
   (2) CHCSII Theater
   (3) FDMR (field version)

b. Integration with medical imaging systems & standards:
   (1) DINPACS
   (2) DTS
   (3) DICOM
   (4) JPEG
   (5) MPEG
   (6) H.323 VTC

c. Integration with portable DoD record devices:
   (1) USAMRMC multimedia personal information carrier (PIC)
   (2) DOD CAC card
   (3) Standard bar code strips

Task 5: Identify scalability requirements for cross platform interoperability inclusive of hand held PC (CE) based PDA through Windows NT operating systems.

A laboratory has been established at both WRAMC Telemedicine Directorate and ViTel Net for use in demonstrating and testing MedVizer tools used in cross platform applications inclusive of hand held PC (CE) based PDA using the Microsoft Windows operating systems in both a wired and wireless environment. The applications discussed throughout this report have been tested in both laboratories with all platforms, demonstrating the scalability function of this tool.

Task 6: Integrate point-of-care data collection, medical order entry, and knowledge acquisition tools with ViTel Net's MedVizer Physician Personal Assistant in a wireless distributed computing environment for military and commercial applications.

The MedVizer integration tools have been used to demonstrate interoperability with:

a. Wireless access to and transmission of medical information via IP/internet
b. 802.11B wireless networks
c. Air Fortress Security Device
d. 128 Bit Encryption System

The MedVizer integration tools have also enabled the successful integration with related USAMRMC research and Congressionally directed projects:

a. Heads up Laser Retina Display (Microvision)
b. Voice capable PDA (PLI) (ongoing)

The MedVizer integration tools have successfully been used to demonstrate automatic input and integration of physiological data from the following medical instruments and sensors:

a. Standard medical scopes & instrumentation devices

    (1) Vital Signs Monitor
    (2) Electronic Stethoscopes
    (3) Electronic Weight Scale
    (4) Micro camera and Endoscopic Devices
    (5) Interoral camera device
    (6) Fundus camera device
    (7) ECG – 12 lead interpretive and 3 lead
    (8) Microscopes
    (9) X-Ray Film Digitizers

b. PCMIA card based input devices

(1) Skin O2
(2) Respirations
(3) Glucose
(4) Spirometer
(5) Temperature

Task 7: Proof of concept: (a) limited fielding prototype system in military and commercial hospital and (b) test and evaluate.

The ongoing projects that have been discussed throughout this report will be used in proof of concept applications. A report will be developed for each project and cross-referenced to the specific SOW tasks involved within the project.

One proof of concept demonstration was conducted at TATRC. This demonstration was conducted during a review of the Combat Support Hospital (CSH) by the Commanding General and other TATRC officials. The demonstration, see Appendix 4, involved using the MedVizer products and tools to enable following the flow of the patient through the field hospital. The MedVizer hand held PDA (CE) was used to create search the existing database for the patient's record and or to create a new record. The PDA was integrated to access patient identification from either the PIC or military medical card using a card scanner. A query was sent wirelessly to the MedVizer Postmaster. Upon receipt the MedVizer Postmaster automatically queried the CHCSII hospital information system to search and present the patient record. If no record were found a new record would be created using the PDA in a format compatible with CHCSII. Then as the simulated patient was processed through the CSH additional data was continuously added to the record by acquiring information from multiple sources to include DINPACS, TOPCON fundus camera, and CHSCII. Healthcare providers at various stages within the CSH, used similar MedVizer wireless hand held PDAs to access the continuously updated patient record and for additional data entry. A project report will be filed describing this demonstration in detail.

KEY RESEARCH ACCOMPLISHMENTS:

The MedVizer Dvision Tools, a commercial-off-the-shelf (COTS) telemedicine integration tool has proven, within a laboratory environment, to be a rapid integration and configuration telemedicine tool. It has been demonstrated within this environment to be capable of dynamically integrating disparate medical teleconsultation systems, medical information and image display modalities, and electronic legacy hospital information systems within a wired and wireless environment.

REPORTABLE OUTCOMES:

Project Reports will be published describing research outcomes. These reports will be distributed as Projects are completed.

CONCLUSIONS:

Execution of the research plan should be applied to specific worthy projects wherein proof of concept applications can be tested and evaluated in military and commercial healthcare systems, which will demonstrate task accomplishments. Each of these projects will have an associated report.

REFERENCES:

References will be provided in project reports.

APPENDIX

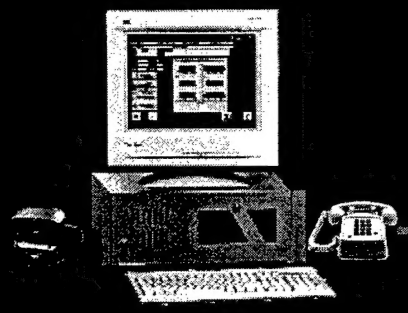
Continuous Care - Outpatient

US Secure Telemedicine

Task 1-1 Data Requirements at Point of Care

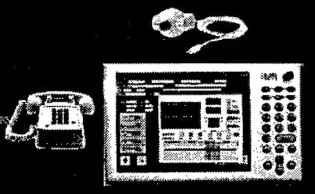
Task 3-1 Integrate Point of Care Data Collection with MedVizer Application

Task 2-1 MedVizer Facilitates Rapid Integration

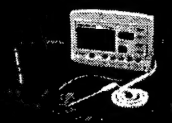


Call Center

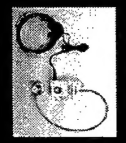
- POTS Video Conferencing
- Pain Scale Form / Vital signs



Home Monitor



Vital Signs Monitor



Stethoscope

Appendix 1

Walter Reed Kiosk / Point of Care Device

US Secure Telemedicine

Task 1-1 Data Requirements at Point of Care

Task 3-1 Integrate Point of Care Data Collection with MedVizer Application

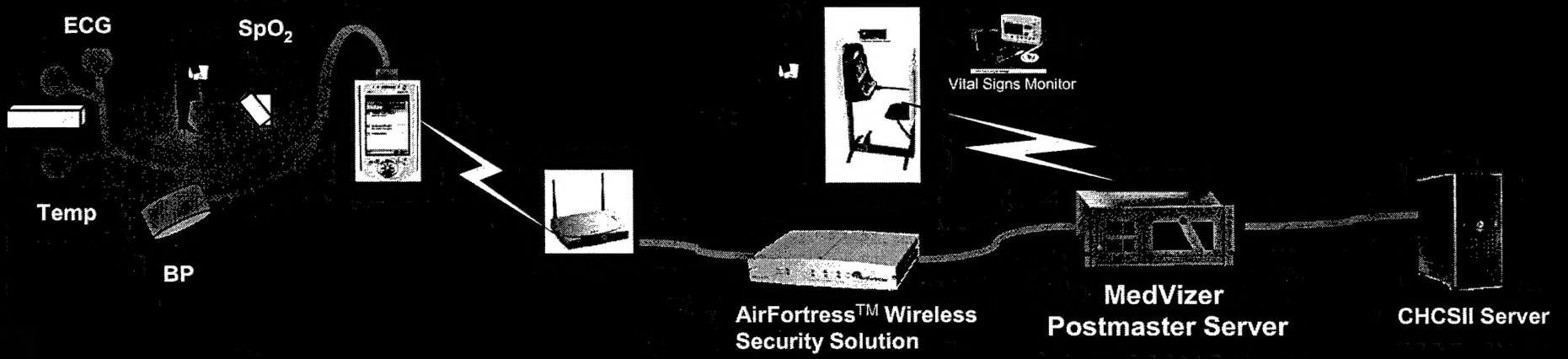
Task 5-1 Interoperability with Legacy HIS Systems

Task 2-1 MedVizer Facilitate Rapid Test & Integration using MedVizer Toolbox

Task 2-2 Integrate MedVizer MPDA with Legacy DoD HIS Systems

Task 3-2 Demonstrate Interoperability of MedVizer with AirFortress 802.11b

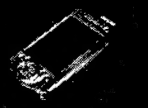
Task 4-2 Integrate Security Protocols into MedVizer PDA (MPDA)



Appendix 2

AirFortress Security Architecture

Unsecured Wireless PDA



AirFortress Client Installed

Secure Wireless PDA

AirFortress Client Installed

Secure Remote Workstation

Access Point

Hub

AirFortress Client Installed

Secure Remote Wireless Workstation

Unsecured Remote Workstation

Secure Firewall

US Secure Telemedicine

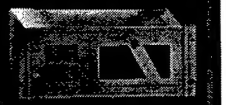
Task 3-2 Demonstrate Interoperability of MedVizer with AirFortress 802.11b

Task 4-2 Integrate Security Protocols into MedVizer PDA (MPDA)

AirFortress Gateway

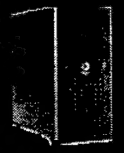
Secure Facility

Hub



AirFortress Server

Secure Local Workstation



Enterprise Server

Appendix 3

Combat Support Hospital (CSH) at TATRC

US Secure Telemedicine

Task 1-1 Data Requirements at Point of Care

Task 2-1 Evaluate commercial clinical medical knowledge data bases

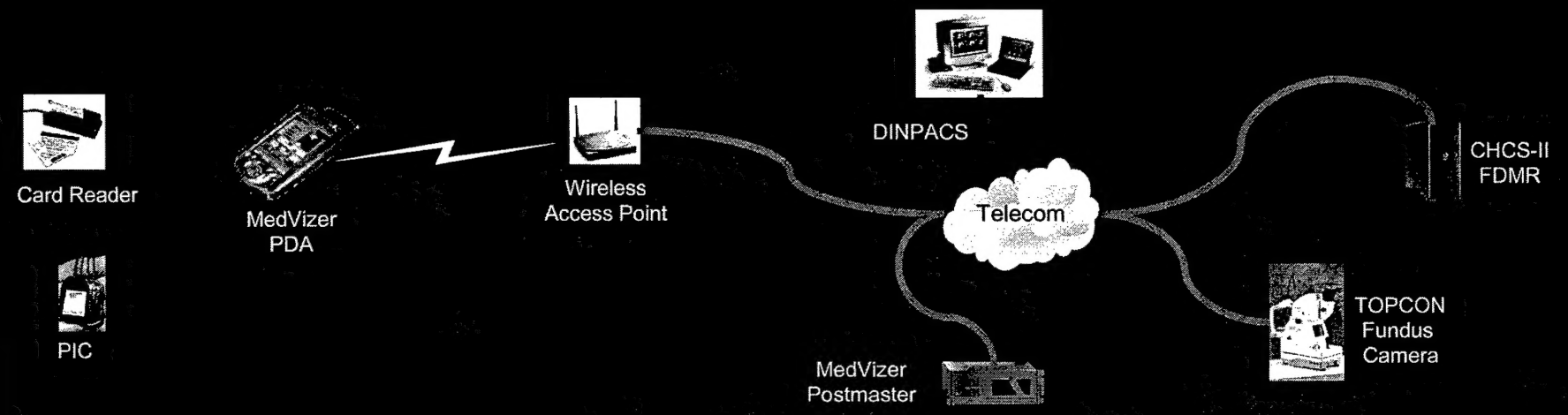
Task 3-1 Integrate Point of Care Data Collection with MedVizer Application

Task 4-1 Establish Wireless Lab to test Point of Care PDA applications

Task 5-1 Interoperability with Legacy HIS Systems

Task 2-1 MedVizer Facilitates Rapid Integration

Task 2-2 Integrate MedVizer MPDA with Legacy DoD HIS Systems



Appendix 4